STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Renée D. Coleman-Mitchell, MPH
Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

Healthcare Quality And Safety Branch

May 7, 2019

Kathleen Silard, President, CEO
Stamford Hospital
One Hospital Plaza
Stamford, CT 06904

Dear Ms. Silard:

An unannounced visit was made to Stamford Hospital on March 27, 2019 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation.

Attached is the violation of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which was noted during the course of the visit.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by May 21, 2019.

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violation and you may be provided with the opportunity to be heard. If the violation is not responded to by May 21, 2019 or if a request for a meeting is not made by the stipulated date, the violation shall be deemed admitted.

An office conference has been scheduled for June 4, 2019 at 11:00AM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting. Please be prepared to discuss those violation(s) identified with an asterisk.

Phone: (860) 509-7400 • Fax: (860) 509-7543
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410 Capitol Avenue, P.O. Box 340308
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THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan Newton, RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:mb

Complaint #24903

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (e) Nursing Service (1) and/or (i) General (6).

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

1.*Based on clinical record review, and interview for 1 of 3 patients (Patient #1) the facility failed to have a mechanism to ensure that laboratory results were communicated to the patient. The findings include the following:

a. Review of Patient #1's clinic record indicated that the patient was seen at the genetic clinic on 6/1/18. The note indicated that an Ovanext panel would be completed and that it was anticipated that the results would be available in three weeks and that the patient would be contacted to discuss them once available. Review of the clinic record indicated that the results were sent to GC #1 via e-mail on 7/3/18. The report indicated that the patient had had a positive BRCA 1/2 result. The clinical record failed to reflect that Patient #1 received notification of the results.

Review of facility documentation provided by the Service Line Director identified an email from GC #1 to the administrative assistant dated 7/5/18 that she left a message for Patient #1 and if the patient returned the call to set up an appointment on 7/6/18, with an addendum that indicated that there was free time on 7/13/18 and to save that time for Patient #1. The record failed to reflect any further documentation/follow-up and/or confirmation that Patient #1 received notification of the results.

Review of the H&P dated 12/30/18 indicated that the patient presented with weakness and cough times one month. The patient had a history of hypertension. The H&P dated 1/11/19 indicated that the patient was scheduled for elective surgery on 1/14/19 for an exploratory Lap secondary to an adenocarcinoid tumor. Review of the 1/14/19 operative note indicated that the patient had stage 4 ovarian cancer. The note indicated in part that a total hysterectomy was completed bilateral salpingo-oopherectomy, total omentectomy, and a low anterior resection with end to end anastomosis and protective colostomy.

Interview with the Service Line Director on 3/27/19 at 1:45 PM indicated in December of 2017 the GC had resigned from her position but agreed to stay on in a per diem capacity. The Director indicated that the GC's last day seeing patients was July 13, 2019. The Director indicated that during the investigation the facility was unable to track communication between the GC and the patient and subsequently had information technology review the phone records.

Interview with GC #1 on 4/4/19 at 3:00 PM indicated that she met with Patient #1 in June of 2018. The GC indicated that the patient's results came back via secure e-mail the beginning of July and that she attempted to contact the patient several time and recalls subsequently talking to the patient and informing the patient to come in for an office visit on 7/13/18 for a full discussion. The GC indicated that the patient did not come to the appointment and that 7/13/18 was her last day and she passed on Patient #1's information to the Administrative Assistant.

Review of the facility correction action plan indicated that an audit was completed of all positive genetic testing results for the previous two years 1/1/17 through 12/31/18 to ensure results were communicated, no reporting delays were identified. A new electronic medical record was implemented that has documentation templates for patient telephone encounters, acknowledgement of test results and communication back to referring provides.

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The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (2) and/or (e) Nursing Service (1) and/or (i) General (6).

2. Based on clinical record review, interview and policy review for 1 of 3 patients (Patient #1) the facility failed to ensure that a comprehensive clinical record was completed. The finding includes the following:

a. Review of Patient #1's clinic record indicated that the patient was seen at the genetic clinic on 6/1/18. The note indicated that an Ovanext panel would be completed and that it was anticipated that the results would be available in three weeks and that the patient would be contacted to discuss them once available. Review of the clinic record indicated that the report was sent to GC #1 on 7/3/18. The report indicated that the patient had had a positive BRCA 1/2 result.

Interview with GC #1 on 4/4/19 at 3:00 PM indicated that she met with Patient #1 in June of 2018. The GC indicated that the patient's results came back via secure e-mail the beginning of July and that she attempted to contact the patient several time however failed to document the calls. The GC recalls subsequently talking to the patient and informing the patient to come in for an office visit on 7/13/18 for a full discussion however indicated that she failed to document this in the record. Review of the clinical record failed to reflect documentation of attempts to contact the patient and/or the outcome.

Review of facility documentation provided by the Service Line Director identified an email from GC #1 to the administrative assistant dated 7/5/18 that she left a message for Patient #1 and if the patient returned the call to set up an appointment on 7/6/18, with an addendum that indicated that there was free time on 7/13/18 and to save that time for Patient #1. The record failed to reflect any further documentation/follow-up.

b. Review of the Clinical Genetics Consultation Note dated 6/1/18 indicated that the patient was seen by GC #1 and MD #1. Interview with the Service Line Director on 3/27/19 at 1:45 PM indicated that MD #1 never saw the patient and that the template used for the note is old.

Review of the H&P dated 12/30/18 indicated that the patient presented with weakness and cough times one month. The patient had a history of hypertension. The H&P indicated that the patient had a strong family history of breast cancer (mother and sister). The H&P dated 1/11/19 indicated that the patient was scheduled for elective surgery on 1/14/19 for an exploratory Lap secondary to an adenocarcinoid tumor.

Interview with the Service Line Director on 3/27/19 at 1:45 PM indicated in December of 2017 the GC had resigned from her position but agreed to stay on in a per diem capacity. The Director indicated that the GC's last day seeing patients was July 13, 2019. The Director indicated that during the investigation the facility was unable track communication between the GC and the patient and subsequently had information technology review the phone records.

Review of the facility correction action plan indicated that an audit was completed of all

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positive genetic testing results for the previous two years 1/1/17 through 12/31/18 to ensure results were communicated, no reporting delays were identified. A new electronic medical record was implemented that has documentation templates for patient telephone encounters, acknowledgement of test results and communication back to referring provides.